



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 876**

**[Docket No. FDA-2021-N-0898]**

### **Medical Devices; Gastroenterology-Urology Devices; Classification of the Pressure Ulcer Management Tool**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the pressure ulcer management tool into class I. We are taking this action because we have determined that classifying the device into class I will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

**DATES:** This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on December 20, 2018.

**FOR FURTHER INFORMATION CONTACT:** Gema Gonzalez, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2530, Silver Spring, MD 20993-0002, 301-796-6519, [Gema.Gonzalez@fda.hhs.gov](mailto:Gema.Gonzalez@fda.hhs.gov)

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Upon request, FDA has classified the pressure ulcer management tool as class I, which we have determined will provide a reasonable assurance of safety and effectiveness. In addition,

we believe this action will enhance patients' access to beneficial innovation by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

## II. De Novo Classification

On April 3, 2017, FDA received Bruin Biometrics, LLC’s request for De Novo classification of the SEM Scanner (Model 200). FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class I if general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(A)). After review of the information submitted in the request, we determined that the device can be classified into class I. FDA has determined that general controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 20, 2018, FDA issued an order to the requester classifying the device into class I. In this final order, FDA is codifying the classification of the device by

adding 21 CFR 876.2100.<sup>1</sup> We have named the generic type of device pressure ulcer management tool, and it is identified as a prescription device intended for patients at risk of developing pressure ulcers. The device provides output that supports a user's decision to increase intervention. The device is an adjunct tool for pressure ulcer management that is not intended for detection or diagnostic purposes.

FDA has identified the following risks to health associated specifically with this type of device: adverse tissue reaction, transmission of infection between patients, electromagnetic interference with patient monitoring equipment, and electrical shock. As previously stated, FDA believes general controls provide reasonable assurance of safety and effectiveness for this device type.

At the time of classification, pressure ulcer management tools are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

Section 510(l)(1) of the FD&C Act provides that a device within a type that has been classified into class I under section 513 of the FD&C Act is exempt from premarket notification under section 510(k), unless the device is of substantial importance in preventing impairment of human health or presents a potentially unreasonable risk of illness or injury (21 U.S.C. 360(l)(1)). Devices within this type are exempt from the premarket notification requirements under section 510(k), subject to the limitations of exemptions in 21 CFR 876.9.

### III. Analysis of Environmental Impact

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<sup>1</sup> FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### IV. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; and the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120.

#### **List of Subjects in 21 CFR Part 876**

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

#### **PART 876--GASTROENTEROLOGY-UROLOGY DEVICES**

1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 876.2100 to subpart C to read as follows:

#### **§ 876.2100 Pressure ulcer management tool.**

(a) *Identification.* A pressure ulcer management tool is a prescription device intended for patients at risk of developing pressure ulcers. The device provides output that supports a user’s decision to increase intervention. The device is an adjunct tool for pressure ulcer management that is not intended for detection or diagnostic purposes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 876.9.

Dated: December 8, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-26924 Filed: 12/10/2021 8:45 am; Publication Date: 12/13/2021]